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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/707,685

Applicant(s)

PALMAZ ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53 and 67-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-53 and 67-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39-53 and 67-74 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Whitcher does not disclose a process condition selected to minimize formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected*. What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit.

Further, applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of such vacuum deposition processes (P0034) therefore, inherently will

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form a product having the same properties and capabilities of the applicant, since the method of production is the same.

Additionally, the applicant has argued that Whitcher discloses only an amorphous film that is annealed into a crystalline film, not a deposited crystalline film. The examiner disagrees. Whitcher discloses both deposition of either an amorphous film (P0041) OR a crystalline film (P0038-P0040, P0043, P0049, P0061, example 1). The applicant also argues that precipitates are formed upon post treatment such as an annealing step. Because Whitcher discloses embodiment wherein the deposited film is crystalline before post treatment, Whitcher's film has no precipitates inherently, according to the applicants admission. This rejection has been maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification did the examiner find support for deposition of a *crystalline* film layer. The only mention of crystallinity is on page 12, lines 1-5, wherein the applicant discusses that the crystalline structure may be controlled, that is, the crystalline

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structure may be any one of subspecies under crystalline structure such as amorphorous, monocrystalline, nanocrystalline, ect. Further, nowhere does the specification disclose that these forms are present before post treatment and during deposition. The specification does not support deposition of an as deposited crystalline film. The statement that the crystal/crystalline structure may be controlled (as disclosed in the specification) and the statement that a deposited film must be crystalline (as claimed) are two different statements with very different scopes, and no support in the specification was found for the second statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited in previous office action). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.2), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035, 0036, 0037]) *selected* (a temp, pressure and rate is disclosed to be

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selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR a crystalline film, see P0038-P0040, P0043, P0049, P0061, example 1), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring to the phrase, process condition “selected to minimize” granular precipitates, Whitcher discloses controlling the microcrystal structure [0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure. Further, inherently the precipitates are controlled, because Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates is dependent upon temp, pressure, and rate, and upon selection of these elements, one has controlled the crystal structure outcome of the metal, hence the precipitates. Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites. Further, applicant noted in their arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher’s methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place. Further, applicant’s disclosure points simply to a vacuum deposition process

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(sputtering and ion-beam evaporation; pg. 11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of such vacuum deposition processes (P0034) therefore, inherently will form a product having the same properties and capabilities of the applicant, since the method of production is the same.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [0034, 0035, 0036, 0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [0034, 0035, 0036, 0037] nickel and titanium [0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [0066], table 1, the deposition occurring under process conditions selected to minimize the formation of granular precipitates in the bulk material of a deposited tubular unpatterned crystalline film (P0038-P0040, P0043, P0049, P0061, example 1), and removing the stent from the substrate [0051, 0052, 0053]. Referring to the phrase, process condition "selected to minimize" granular precipitate, Whitcher discloses controlling the microcrystal structure [0011, 0028, 0038, 0042,

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0043], therefore, inherently the granular precipitates are controlled/minimized, since granular precipitates are an element of a materials microstructure. Further, inherently the precipitates are controlled, because Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates is dependent upon temp, pressure, and rate, and upon selection of these elements, one has controlled the crystal structure outcome of the metal, hence the precipitates. Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled/minimized by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling/minimizing* the grain size, grain phase, granular precipitates, composition, and binding sites.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

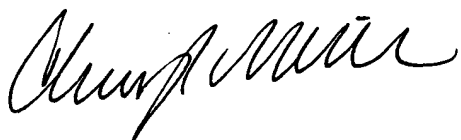
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



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